# COMMUNICATION OF DRUG SAFETY INFORMATION TO PHYSICIANS: AMERICAN MEDICAL ASSOCIATION PERSPECTIVE

**By**
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**At**
**FDA Part 15 Hearing**
**December 8, 2005**

Good morning. My name is Joseph Cranston. I am a pharmacologist by training, I currently serve as the Director of Science, Research and Technology at the American Medical Association (AMA), and I am speaking on behalf of the AMA at this Part 15 Hearing. The focus of my comments today will be on the communication of drug safety information – or risk communication - to physicians.

The AMA shares a common goal with the FDA and other stakeholders that there is a need to optimize the benefit/risk balance of drug therapy. Improving the safe use of prescription drug products after they are marketed is a primary means to achieve this goal. In June 2005, the AMA's House of Delegates, our policy-making body, adopted the recommendations of our Council on Scientific Affairs' report entitled, "Enhanced Physician Access

to Food and Drug Administration Data," that address postmarketing drug safety issues. The key recommendations are as follows:

1. The FDA should issue a final rule, as soon as possible, implementing modifications to the format and content of professional labeling, i.e., the Package Insert, with the goal of making the information more useful and user-friendly to physicians.
2. The FDA should collaborate with physician organizations to develop better risk communication vehicles and approaches.
3. The FDA should apply new tools to gather data after drugs are approved for marketing, including broader use of targeted post-approval studies, institution of active and sentinel event surveillance, and data mining of available drug utilization databases. And
4. There must be adequate funding of FDA to implement an improved postmarketing prescription drug surveillance process.

For the remainder of today's presentation, I will discuss the AMA's views on improving risk communication about marketed prescription drugs to physicians. Most of what I will say is a re-affirmation of previous comments that the AMA has provided on risk communication to the FDA,

the Senate Committee on Health, Education, Labor and Pensions, and the Institute of Medicine's Committee on the Assessment of the United States Drug Safety System. However, I also will comment on some of the risk communication tools that are of particular interest to the FDA, as listed in the *Federal Register* Notice announcing this public meeting.

Professional Labeling (Package Insert)

While technically outside of the scope of today's Hearing, the FDA-approved Professional Labeling, or Package Insert (PI), must be discussed because this is the primary mechanism by which physicians obtain safety information about a prescription drug product. The AMA strongly agrees with the FDA that the Package Insert, updated from time-to-time to incorporate information from postmarketing surveillance, should be the routine risk minimization plan for the vast majority of drug and biological products. The information provided in the Package Insert, along with other information about a product, such as published clinical trials, should remain the standard method of providing benefit and risk information to physicians about the use of a drug or biological product.

However, as previously communicated to FDA, the AMA believes that the current Package Insert for prescription drugs is a barrier to effective risk communication. As one of the results of our nation's medical liability crisis, the Package Insert has become a complex legal document to protect the manufacturer rather than a useful resource for busy practicing physicians. In December 2000, the FDA issued a Proposed Rule to modify the format and content of the Package Insert with the goal of making the information more useful and user-friendly to physicians. The AMA has supported this effort, especially the proposed "Highlights of Prescribing Information." The AMA urges the FDA to issue a Final Rule implementing these changes to the Package Insert as soon as possible.

Furthermore, there is a need for a readily available electronic database of the most up-to-date prescription drug labeling for all products, in lieu of the hard-copy *Physicians Desk Reference (PDR)* that is both cumbersome and dated for certain products. In that regard, the AMA commends the FDA for its recent announcement that it will now require manufacturers to submit drug product labels electronically, and that it will create an electronic database of up-to-date Package Inserts for all products.

Improving Risk Communication Beyond the Package Insert

As postmarketing surveillance uncovers important new safety information about a prescription drug or biological product, there must be effective mechanisms to ensure that physicians are aware of this new safety information. This is especially important when a new and serious adverse event can be prevented or minimized by modifications in prescribing behavior. Under these circumstances, physicians need to be more than just aware of the problem. They need to put this new safety information into action and prescribe the drug appropriately to prevent the adverse event from occurring.

There is evidence that traditional "Dear Doctor" letters have been relatively ineffective as a means to communicate new risk information about marketed drugs to physicians. Thus, more innovative and effective approaches to inform and educate physicians about risk need to be developed.

In its *Federal Register* Notice for this Hearing, the FDA requests feedback on various risk communication tools that the Agency has developed. It is fair to say that FDA Talk Papers, Public Health Advisories, Press Releases, MedWatch Listserv Safety Updates, and Patient Safety News videos are all

methods that can provide important, timely, and accurate information about new risks of drug products. However, one must either proactively seek out this information by routinely accessing the FDA's web site, or participating in various CDER ListServs that email all types of new information, including non-urgent information, to users on a frequent (i.e., almost daily) basis.

While we do not have objective data, the AMA believes that most busy practicing physicians will lack the time to actively seek out new drug safety information from the FDA's multiple sources. What is required are innovative mechanisms to both filter – or prioritize – the FDA's valuable information, and more effectively deliver it to physicians so they will be aware of it and act accordingly.

The AMA believes that the FDA, the pharmaceutical industry, and physician organizations – especially medical specialty societies - must collaborate and identify innovative ways to communicate new risk information about drugs and biological products to physicians so they will be aware of it, remember it, and act on it when prescribing a drug. In prior comments to the Agency,

the AMA presented a number of potential ways to accomplish this goal. Most of these options could be implemented immediately, including:

1. The FDA, the pharmaceutical industry, and physician organizations should undertake a major CME initiative on risk communication. Physicians need to be aware of labeling changes that identify serious adverse events and that, in some cases, these serious adverse events can be minimized by modifications in prescribing. The AMA's recommendations that the FDA publish its final rule on the Package Insert and create a computerized database of up-to-date Package Inserts, as discussed above, should be implemented as part of this education initiative.
2. The FDA, in collaboration with physician organizations, should work with major medical journals and medical society web site editors to identify standard places for the dissemination of important new risk information about drugs and biological products.
3. "Dear Doctor" letters should be disseminated by mechanisms other than hard-copy mail. Alternative mechanisms could include publication in medical journals, placement on medical society web sites, and transmission to individual physicians by blast fax, blast email, and direct downloads to personal digital assistants (PDAs). Unlike letters,

electronic transmission is inexpensive, timely, and repeatable. Thus, important risk information can be reinforced by more than one transmission.

4. The content and format of "Dear Doctor" letters should be changed to emphasize the need for action by the prescribing physician. For example, a "Dear Doctor" letter could contain a bold-faced opening paragraph that emphasizes the possible severe outcome (e.g., permanent harm or death) to patients from the new adverse event, that the adverse event is probably preventable if the drug is used appropriately, and what necessary steps the physician must take to prescribe the drug appropriately.
5. Pharmaceutical companies, under appropriate FDA oversight, should be obliged to train and send their sales forces to physicians to educate them on important new risk information about company products. The company should provide incentives to sales representatives to do this because the highest priority of any company should be to prevent harm to patients who use their products. The effectiveness of the 90,000 pharmaceutical sales representatives in the United States in promoting the benefits of their companies' products is well documented, and they could have similar success in educating physicians about important new safety problems.

6. New information technologies, such as electronic prescribing, offer enormous opportunities to communicate important risk information about drug and biological products. E-prescribing systems with well-designed decision support programs potentially could communicate important new risk information to physicians at the point of prescribing, i.e., at a time when the information is most needed. As these new information technologies become integrated into physician practice, the FDA, the pharmaceutical industry, and physician organizations should work with database providers and software vendors to incorporate the appropriate risk information into these electronic systems.

Again, the AMA encourages the FDA and the pharmaceutical industry to work with physician organizations to optimize physician education about the risks of drug and biological products through identification and implementation of effective methods of risk communication.

Healthcare Professional Information Sheets

Finally, I would like to comment on the FDA's proposed Healthcare Professional Information Sheets as a risk communication tool. As previously stated in our August 2005 letter to FDA on its "Drug Watch"

draft guidance, the AMA does not support the development of Healthcare Professional Information Sheets because it will result in redundant, and perhaps confusing, information for physicians who rely primarily on the Package Insert.

Instead, the AMA recommends that the FDA invest its resources into developing a high quality Drug Watch web page for emerging drug safety information, that would include the following information for a drug product that appears on the web page:

1. The FDA Alert describing the emerging safety concern;
2. A brief summary of the available evidence that warranted inclusion of the drug product on Drug Watch;
3. Advice – but not mandates – for physicians on potential changes in prescribing of the product, when warranted;
4. A disclaimer that this is preliminary information and no final regulatory action has been taken; and
5. Linkage only to the professional labeling, i.e., the Package Insert.

As discussed earlier, the final rule for the revised Package Insert, with a "Highlights of Prescribing Information" section, should also be among the

Agency's highest priorities. Linking a Drug Watch citation, with the information listed above, to the Package Insert will be more useful and user-friendly to physicians, as opposed to creating a whole new database of Healthcare Professional Information Sheets.

This concludes my formal presentation and I would be happy to entertain any questions.